REMARKS

The Office Action

Claims 1-22 were pending in this application. With this reply claims 2, 3, 5-7, 9, 10, 12-15, and 20-22 have been canceled for being directed to unelected subject matter. Claims 17-19 have been rejoined to the scope of elected group II. Thus, with this reply claims 1, 4, 8, 10, 11, 16, and 17-19 are pending. Claims 1, 4, 8, 10, 11, 16, and 17 are objected to as containing non-elected subject matter. Claims 18 and 19 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description.

Objections to the claims

Claims 1, 4, 8, 10, 11, 16, and 17 are objected to as containing non-elected subject matter. Applicants have addressed this rejection by amendment of claim 1 to remove the non-elected subject matter.

In view of this amendment, applicants request withdrawal of this objection to the claims.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 18 and 19 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description. The Office asserts that the term "diseases due to dopamine dysregulation" does not convey to one of skill in the art that applicants were in possession

of the claimed subject matter because with the recitation of this function alone one of skill in the art cannot recognize or understand which diseases/disorders are to be treated. Furthermore, the Office asserts that rejection for lack of written description is proper where the claims employ functional language at the point of novelty and claims encompass the treatment of diseases not yet discovered. Applicants respectfully disagree.

To fulfill the written description requirement of § 112, the patent specification does not need to describe exactly all the subject matter that is claimed. *In re Daniels*, 114 F.3d 1452, 46 U.S.P.Q.2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 117 (Fed. Cir. 1985). Rather, the specification must clearly allow a person of ordinary skill in the art to recognize that the inventor has invented what is claimed. *Gentry Gallery, Inc. v. Berkline Corp.,* 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). Further, under *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1159, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), "every species in a genus need not be described in order that a genus meets the written description requirement." 43 U.S.P.Q.2d at 1405 (citing *Utter v. Hiraga*, 845 F.2d 993, 6 U.S.P.Q2d 1709 (Fed. Cir. 1988) ("A specification may, within the meaning of § 112, ¶ 1, contain a written description of a broadly claimed invention without

describing all species that claim encompasses"). Applicants have met these standards.

Applicants' specification would certainly indicate to one of ordinary skill in the art that Applicants invented a new class of compounds which bind to opioid receptors and new methods for treating disease which include the step of administering the new compounds. The specification clearly describes to the skilled worker the subject matter of claims 18 and 19. Claims 18 and 19 are directed to the use of these compounds for the treatment of dopamine dysregulation diseases, such as schizophrenia, attention deficit hyperactivity disorder, attention deficit hyperactivity disorder, Parkinson's disease, hyperprolactinemia, depression, and addiction. With respect to the relationship between dopamine levels and the compounds of the invention, the specification, at page 15, lines 13-18, recites:

> The *mu/kappa* opioids described herein can be used to modulate dopamine levels for the treatment of dopamine dysregulation diseases, such as schizophrenia, attention deficit hyperactivity disorder (ADHD), attention deficit hyperactivity disorder (ADD), Parkinson's disease, hyperprolactinemia, depression, and addiction.

With respect to the meaning of dopamine dysregulation disease, the specification, at page 8, lines 10-14, recites:

> By "dopamine dysregulation disease" is meant a disease characterized or mediated by abnormal levels of dopamine in the brain. Examples of dopamine dysregulation diseases include schizophrenia, attention deficit hyperactivity disorder (ADHD), attention deficit hyperactivity disorder (ADD), Parkinson's disease, hyperprolactinemia, depression, Tourette's syndrome, and addiction.

The use of opioids for the treatment of dopamine dysregulation diseases was known to those of skill in the art at the time of filing.

Applicants note that at the time of filing the kappa opioid receptor was known to influence, via indirect effects, synaptic dopamine levels and this effect had been exploited therapeutically. For example, it was known that opioid receptor agonists, particularly kappa receptor agonists, can modulate the neurochemical and behavioral effects of cocaine by inhibition or attenuation of the release of dopamine from dopaminergic neurons following cocaine administration. See Exhibit A, Thompson et al., *The Journal of Neuroscience*, 20:9333 (2000). Addiction is a disease characterized by dopaminergic dysregulation. The compounds of the invention are active at kappa opioid receptors and, therefore, can be administered to correct the abnormal dopamine levels associated with a dopamine dysregulation disease.

The point of novelty in claims 18 and 19 is the identity of the compounds being used.

Applicants note that the point of novelty in claims 18 and 19 is the identity of the compounds being administered, not the diseases being treated. The present rejection is based, in part, on the conclusion that claims 18 and 19 employ functional language at the point of novelty. However, claims 18 and 19 incorporate the structural limitations of the compounds of claims 1, 4, 8, 10, and 11. Without these structural limitations, claims 18 and 19 would lack novelty over, for example, the Thompson reference, submitted

herewith, and the Neumeyer references submitted with our last reply. Accordingly, the point of novelty in claims 18 and 19 is the structures of the claimed compounds employed in the method and not the function of dopamine dysregulation characteristic of the disorders to be treated.

Applicants are not required to teach all possible species.

The present rejection is also based, in part, on the possibility that claim 18 encompasses the treatment of diseases not yet discovered. Applicants note that the specification need not teach all species to satisfy the written description requirement for a claimed genus. To provide further support for this position, Applicant directs the Office's attention to M.P.E.P. § 2163.II.A.3(a) (emphasis added):

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by...**disclosure of relevant, identifying characteristics**, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... **[T]here may be situations where one species adequately supports a genus**. See, e.g., Rasmussen, 650 F.2d at 1214, 211 USPQ at 326-27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered)...

As described above, the instant specification provides sufficient disclosure of relevant, identifying characteristics of the claimed invention. It is not necessary to list all species within the genus. Indeed, all that is required is a characterization of the essential

functional elements of members of the genus. In the present case, the essential functional element of the genus is that each disease is characterized by abnormal levels of dopamine in the brain. One of skill in the art would immediately recognize that any such disease could be treated using a compound which modulates the release of dopamine from dopaminergic neurons, such as the compounds of the invention.

In view of the arguments above, applicants request that the rejection for lack of written description be withdrawn.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested. To expedite prosecution Applicants request a telephonic interview with the Examiner to discuss any remaining rejections. The Examiner is invited to call the undersigned at 617-428-0200.

Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including Monday August 14, 2006, as August 13, 2006, fell on a Sunday, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045